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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,831	12/09/2003	Wayne P. Franco	0147-1 DIVI	5378

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EXAMINER	
GAMETT, DANIEL C	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,831	FRANCO, WAYNE P.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20-24,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,20-24,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/19/2006 has been entered. Claims 16, 20-24, 27, and 28 are under examination.
2. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:
5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first

paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

6. The disclosure of the prior-filed application, Provisional application no. 60/195624 provides support for methods comprising administration of the genus of VEGF, but does not provide motivation to select the species PIGF recited in the instant claim. PIGF is not mentioned in 60/195624. Accordingly, priority for the instant claims is 04/06/2001, the earliest date on which this exact disclosure was filed.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 16, 20-24, 27, and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 11, 12, 13, 14, 15, 20, and 23 of

U.S. Patent No. 6,759,386 (6 July 2004) Franco, in view of WO 200156593, filed 5 February, 2001. The currently amended claims are distinguished from claims 1,11, 12, 13, 14, 15, and 20 of the '386 patent by the recitation of PIGF as opposed to VEGF; the claim sets are otherwise identical as set forth in the prior statutory double patenting rejection. The instant specification is consistent with prior art in teaching that PIGF and VEGF are members of a family of structurally related growth factors. WO 200156593 teaches (Example 3, page 18) that treatment of infarcted mice with PIGF stimulated the formation of new endothelial-lined vessels (angiogenesis) and the maturation of these coronary vessels by coverage with vascular smooth muscle cells (arteriogenesis) in the ischemic myocardium better, in all types of vessels, than the treatment of infarcted mice with VEGF. WO 200156593 further teaches (Example 5, page 20) that VEGF causes hypotension, whereas PIGF has no systemic hemodynamic side effects. Thus it would have been obvious to one of skill in the art at the time the instant invention was made to choose PIGF as the VEGF family member to use in the claimed methods with a reasonable expectation of success, and with an expectation of superior results. Therefore, the instant claims represent an obvious embodiment and are not patentably distinct from the generic claims of the '386 patent.

9. Claim 9 and 23 of the'386 patent recite species of the claimed method which would anticipate embodiments of the generic instant claims 16 and 24, wherein either FGF-1 or FGF-2 is the selected growth factor protein.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 16, 20-24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 200156593. WO 200156593 teaches (Example 3, pages 17-18) that treatment with PIGF, VEGF, or both, stimulated the formation of new endothelial-lined vessels (angiogenesis) and the maturation of these coronary vessels by coverage with vascular smooth muscle cells (arteriogenesis) in an animal model of heart disease. These teachings anticipate or at least render obvious the administration of these factors for the treatment of all conditions recited in the instant claims, as the observed effects would be expected to be beneficial in all cases. WO 200156593 further teaches chronic administration, i.e. several doses over a period of several days, which anticipates step a) and at least renders obvious the administration of one or more additional doses as recited in the instant claims at step e). Steps b-d of instant Claims 16 and 24, provide for monitoring the effectiveness of the treatment and making a determination of whether to administer additional doses of growth factors or to discontinue treatment. Monitoring results and making decisions as to whether to

repeat or discontinue treatment are intrinsic to all methods of treatment. The claims do not recite any novel monitoring method or decision-making process that would not be obvious to one of skill in the art. WO 200156593 further teaches that that PlGF and VEGF can be formulated into compositions that can used as dusts, sprays, aerosol, or powders, thereby anticipating inhalation therapy as required by claims 16 and 24, step a) and claims 20, 21, 27, and 28.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
27 March 2006